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Patient choice compared with no choice of intrathecal morphine dose for caesarean analgesia: a randomized clinical trial

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Abstract

Background: The study aimed to determine whether a patient's choice for their intrathecal morphine (ITM) dose reflects their opioid requirements and pain after caesarean delivery and if giving women a choice of ITM dose would reduce opioid use and improve pain scores compared with women who did not have a choice.
Methods: A total of 120 women undergoing caesarean delivery with spinal anaesthesia were enrolled in this randomized, double-blind study. Patients were randomly assigned to a choice of 100 or 200 μg ITM or no choice. The study involved deception, such that all participants were still randomly assigned 100 or 200 μg ITM regardless of choice. Rescue opioid use over the 48-h study period was the primary outcome measure. Pain at rest and movement and side effect (pruritus, nausea, and vomiting) data were collected 3, 6, 12, 24, 36 and 48 h postoperatively. Data are presented as median [95% confidence interval (CI)].
Results: Women who requested the larger ITM dose required more supplemental opioid [median 0.8 (95% CI 0.4–1.3)] mg morphine equivalents at each assessment interval; $P < 0.001$] and reported more pain with movement [median 1.2 (95% CI 0.5–1.9)] verbal numerical rating score of 0–10 points] than patients who requested the smaller ITM dose ($P = 0.0008$), regardless of the ITM dose given. There was no difference in opioid use whether the patient was offered a perceived choice or not.
Conclusions: Women who were given a choice and chose the larger ITM dose correctly anticipated a greater postoperative opioid requirement and more pain compared with women who chose the smaller dose. Simply being offered a choice did not impact opioid use or pain scores after caesarean delivery.
Trial Registration: ClinicalTrials.gov (NCT01425762).

Key words: analgesia; caesarean section; intrathecal morphine; pain

Pain after caesarean delivery (CD) is described as moderate to severe and is often incompletely relieved by modern pain management protocols.[1] Women with severe acute post-CD pain have an increased risk of persistent incisional pain compared with those who report mild acute postoperative pain.[2] With >1.4 million CDs now performed annually in the USA, strategies to reduce adverse maternal outcomes, including postoperative pain, have important clinical and public health implications.

Analgesic drug dosing requires offsetting desired analgesic effects against expected drug-related side effects. The

Editor's key points

- The relationship between patient expectation of analgesic need and actual pain relief required is unclear.
- This study explored how choice (high- or low-dose morphine) or no choice affected pain.
- A higher dose choice was associated with greater pain scores and analgesic consumption, regardless of the actual dose received.
- Concern for pain or side effects impacted how women chose an intrathecal morphine dose.
- Further work is needed to explore the use of patient involvement in improving postoperative analgesia.

traditional physician-oriented models require the clinician to use standardized 'one-size-fits-all' pain management protocols or their expert opinion to select analgesic doses without soliciting patient input to guide the balance between analgesia and potential opioid-related side effects. Intrathecal morphine (ITM) is a very effective postoperative analgesic strategy utilized in the majority of women undergoing CD in the USA.[3] However, there is considerable heterogeneity among expectant women's desires for pain relief and potential side effect avoidance after CD.[4] A study found that simply asking patients preoperatively about anticipated pain, expected pain medication needs, and anxiety accounted for 20% of the variability in post-caesarean pain.[5] Effective pain management is an essential element of postoperative outcome; the Joint Commission recommends postoperative pain score of not >3 out of 10, both at rest and with movement. The patient's involvement in analgesic drugs and dosage selection based on individual desires for pain relief after surgery and concern for side effects may potentially improve the alignment between patient expectation and outcome.

The primary aim of the study was to investigate whether a patient's choice for their ITM dose would be reflective of their CD pain and postoperative opioid analgesic use. We hypothesized that giving women a choice to select their ITM would have a positive analgesic effect and that women would be able to anticipate their analgesic needs such that those preferring a larger ITM dose would have higher postoperative analgesic requirements and greater pain scores. Secondary outcomes included side effect differences between women preferring a lower compared with a higher dose, as well as pain scores, opioid requirements, and side effect differences between the 100 and 200 μg ITM doses received.

Methods

Study design, setting, and sample population

The study was a prospective, randomized, double-blind, single-centre study of 120 women undergoing CD. After approval by the Stanford University Institutional Review Board (Stanford, CA, USA), we approached consecutive patients who fulfilled study criteria to participate. Patients were invited to take part in the study if they were scheduled for CD with spinal anaesthesia and were 18–45 yr of age with a singleton, term (>37-weeks gestation) pregnancy. Written informed consent was obtained from all women who agreed to participate. The consent informed participants that they would be randomized to a choice or a no choice group. The 'no-choice" group was informed they would be randomized to a group that would receive either 100 or 200 μg ITM. The 'perceived-choice' group was not told they would be still randomized to receive either 100 or 200 μg ITM. Deception in the choice group could obviously not be disclosed in the consent, however, all participants received a debriefing letter after the study to explain the study design and that deception was used. Before patient enrolment, the study was registered on August 25, 2011, at http://www.clinicaltrials.gov (NCT01425762).

A history of significant medical or obstetric disease; contraindication to neuraxial anaesthesia; failed neuraxial anaesthesia requiring conversion to general anaesthesia; chronic pain, anxiety, or depression; use of antidepressants or anticonvulsants during the pregnancy; and intolerance or allergy to opioids, non-steroidal anti-inflammatories, or local anaesthetics were exclusion criteria. Subjects were also excluded who had taken opioids, acetaminophen, or non-steroidal anti-inflammatory drugs within 48 h of surgery. Women were enrolled at their preoperative anaesthetic evaluation before their CD and written informed consent was obtained. The study was conducted at Stanford Children's Hospital, Palo Alto, CA, USA from August 2011 to August 2013 and was stopped when the pre-stated sample size was enrolled.

The study involved two potential doses (100 and 200 μg) of ITM for postoperative pain management. Using a computer-generated list of random numbers, we assigned patients to one of two groups: perceived choice and no choice. In the perceived-choice group, patients were offered a choice of 100 or 200 μg ITM after being read a standardized script that discussed the trade-off of pain relief after their CD with a possible increased risk of the most common opioid-related side effects—nausea, vomiting, and pruritus (appendix). However, the study involved deception such that the patient's choice was recorded but did not influence the actual dose of ITM administered. Instead, patients in the perceived-choice group were randomly assigned 100 or 200 μg of ITM. In the no-choice group, the patients were not offered a choice of ITM dose, and similarly received a randomly assigned dose of 100 or 200 μg of ITM. Figure 1 shows the enrolment and randomization diagram. Randomization was done before study commencement using the Excel (Microsoft, Redmond, WA, USA) random number generation function by an investigator not involved in enrolment. Simple randomization without stratification was utilized. Group assignments were contained in opaque envelopes to ensure blinding of the investigators. Patients, study investigators, and data analysts were blinded to group assignments. The anaesthesiologists administering the anaesthesia were not involved in data acquisition or analysis. The physician caring for the patient had no knowledge of the dose selection or group assignment (perceived choice vs. no choice). The Stanford University Institutional Review Board approved the use of deception as part of the study methodology. The aims of the study could not be accomplished without the use of deception, and the Institutional Review Board agreed that deception posed minimal risk to the patients. Patients were not informed at enrolment or during the study that deception was being utilized, as this knowledge would have potentially confounded the study results. After the study was completed and the data analysed, debriefing letters were sent to all patients who were deceived as part of the study design explaining the study methodology and use of deception.

Study protocol

All patients received spinal anaesthesia with intrathecal hyperbaric bupivacaine 12 mg, fentanyl 10 μg, and morphine 100 or 200 μg ITM as per randomization. The 100 and 200 μg ITM doses